

## CONTEMPORARY TRENDS IN THE IMPROVEMENT OF QUALITY MANAGEMENT SYSTEMS IN CHEMICAL LABORATORIES

***Radoslav Grujić<sup>1</sup>, Mira Obradović<sup>1</sup>***

<sup>1</sup> PI College of Health Science Prijedor, Nikole Pašića 4A, Prijedor, Republic of  
Srpska, Bosnia and Herzegovina

**Abstract:** *Medical and clinical laboratories play an important role in the public health care system. The efficiency of the overall system and the success in reaching the set goals depend on the quality management system in organizations whose activity is related to the examination of material samples obtained from the human body. Current regulations are mostly of a generic nature. The requirements of the laboratory's quality management system should be adapted to the conditions and specific work activities. The aim of this paper is to present the requirements of quality management standards and analyze the possibility of their application in a chemical laboratory where medical laboratory engineering students are trained. The paper provides an overview of the key requirements of three standards: ISO 9001, ISO 15189 and ISO 17025. The ISO 9001 standard is intended for the certification of organizations of all types and sizes, including medical and health laboratories, while the ISO 17025 standard is intended for the application and accreditation of all laboratories dealing with testing and calibration. The ISO 15189 standard, which is based on the Principles of Good Laboratory Practice, is intended for use exclusively in medical and clinical laboratories. According to the requirements of ISO 9001, the fulfillment of all requirements should result in client satisfaction and full compliance with regulations. The standard is based on certain principles, however the standard does not contain technical requirements specific to laboratories. On the other hand, the ISO 15189 standard is focused on technical requirements for medical and clinical laboratories, including laboratories for chemical test. This standard adapts the requirements of ISO 17025 for application to medical and clinical laboratories. The requirements of the ISO 15189 standard are complementary to the current regulations and significantly supplement their application in practice. Based on the analysis of the valid versions of the quality management standards, it can be concluded that it is desirable for chemical laboratories to simultaneously implement the ISO 9001 and ISO 15189 standards while respecting the official regulations in this area.*

**Keywords:** *Medical and health laboratories, chemical laboratory, Quality management system, ISO 9001, ISO 15189, ISO 17025*

### Introduction

A laboratory is a body that performs one or more of the following activities: testing, calibration (standardization) and sampling [1]. Sampling activity is related to testing and calibration, that is. activities that follow after sampling. Medical laboratories are specific bodies where biological, microbiological, immunological, chemical, immunohematological, hematological, biophysical, cytological,

pathological, genetic or other tests of materials obtained from the human body are performed [2]. During these examinations, information is obtained on the basis of which diagnoses are given, and monitoring, prevention and treatment of diseases is carried out, or human health is assessed. Tests in medical laboratories are carried out according to a procedure for determination and measurement or according to an instruction that otherwise describes the presence or absence of various substances or microorganisms [2].

Most clinical decisions are based on the results of laboratory analyses, which is why timely reporting of the results is important [3]. Laboratories implement a quality management system to ensure that accurate and reliable results are obtained and that they are published in a timely manner, including quality assurance. Quality management ensure the competence and reliability of procedures in all phases of work: from taking patient samples (preanalytical phase), through sample handling and testing (analytical phase), to analysis and reporting of patient results (postanalytical phase) [4, 5].

The term "quality" has a relative meaning. This is expressed by the ISO definition: "The degree to which a set of inherent (inherent) characteristics fulfills the requirements" [2]. In simpler terms, a product/service is of good quality when it "conforms to the requirements specified by the client". When projected onto the analytical work of medical laboratories, quality can be defined as "the delivery of reliable information within an agreed time period under agreed conditions, at agreed costs and with the necessary follow-up care". The "agreed conditions" should contain the specification of the precision and accuracy of the data which is directly related to the "suitability of use" and which may differ for different applications. Many laboratories operate according to established methods and procedures that are not easily changed and have inherent default specifications. Moreover, not all future uses of the data and reports can be foreseen, so specifications on the required precision and accuracy cannot be given. Consequently, this aspect of quality is usually left to the discretion of the laboratory [6].

The quality of a laboratory can be defined as the accuracy, reliability and timeliness of the submitted test results. Test results must be accurate, all aspects of laboratory operations must be reliable, and reporting of results must be timely [7]. A certain level of inaccuracy always exists in testing. The challenge for the laboratory is to reduce the level of imprecision as much as possible, while respecting all the limitations of the testing system. If the laboratory gives incorrect results, it can have negative consequences (for example, unnecessary treatment, complications during treatment, delay in correct diagnosis, additional diagnostic tests required) [7]. It is difficult to avoid variation in results and laboratory errors. The quality system applied by the laboratory must minimize all influences on the obtained results. In this case, the measurement uncertainty must be taken into account.

The development and implementation of a comprehensive quality system in the laboratory is based on good laboratory practice (GLP), quality management (QM), quality assurance (QA) and quality control (QC) [8]. A well-established and functional quality management system is an integral part of every diagnostic

laboratory [9]. Quality management (QM) encompasses the management of all activities in the organization and aims to achieve the expected quality of service they offer to the client. The result achieved through activity management is known as quality assurance (of products and/or) services that the laboratory provides to the client. Quality control (QC) includes various techniques used by laboratories to achieve and maintain the expected quality (of products and/or) services they provide to the client [6]. In terms of medical laboratories, quality control (QC) can be defined as a constellation of mechanisms used to determine the accuracy, reliability and consistency of data, tests performed in a laboratory [10]. QC is primarily focused on documenting specific actions performed in the laboratory, for the purpose of ensuring quality and preventing possible errors that may affect the implementation of the analysis procedure or the results that the laboratory provides. QC in the laboratory acts as a safety net and enables the establishment of a QMS and the generation of reliable data. Errors in the analyst's work are inevitable. When a laboratory has a functional QC, errors will be detected, which will enable process improvement and error elimination [8]. In the context of laboratory testing, QA is the sum of all processes and activities undertaken to ensure that results are accurate, reliable and produced on time [11]. QA and QC support the management structure and ensure that the laboratory provides reliable data.

Certified reference materials are an integral part of laboratory QA/QC in chemical analysis laboratories. The use of certified or standardized reference materials is necessary to establish accuracy in chemical analysis, to internally validate the method for the laboratory, and to provide a tool for determining traceability [8]. Traditional control materials in some situations remain unchanged and insensitive to tests with low analytical performance [12, 13]. Multiple studies [14, 15, 16] have shown that real-time quality control (PBRTQC) techniques, which are based on the patient, are very suitable during routine tests of analytical system performance. Most importantly, PBRTQC practice directly links analytical system performance to patient outcomes and utilizes data already available in the information system.

The International Organization for Standardization (ISO) and the Clinical and Laboratory Standards Institute (CLSI) defined a quality management system (QMS) as "coordinated activities to direct and control the quality of an organization" [7]. This definition is used by the Quality Management System, which covers all aspects of laboratory work, including organizational structure, processes and procedures. Quality management in the current context can be considered a modern version of the concept of "Good Laboratory Practice" (GLP) [6]. The OECD document defines GLP: "Good laboratory practice (GLP) deals with the organizational process and conditions under which laboratory studies are planned, performed, monitored, recorded and reported" [17]. A QMS is a system that ensures that a laboratory develops and adheres to guidelines given in the form of various documents (for example, a quality manual, quality procedures, technical procedures, administrative procedures, work instructions and record keeping requirements) [8]. Several models for QMS have been proposed. One of the proposed models is the model of the Institute for Clinical and Laboratory Standards, which defines 12 essential

components of QMS [18]. WHO proposed this model in its Laboratory document quality management system: handbook [7].

Hooijberg [4] lists the following elements of a quality management system: formulation of a quality plan, establishment of quality objectives, health and safety policy, personnel training, appropriate and good maintenance of facilities and equipment, standard operating procedures and participation in external quality assurance programs. In order to monitor the efficiency of the management system, laboratories apply various quality indicators. In practice, accuracy, precision, timeliness and reliability are most often used [19]. In order to deliver test results to users on time, some laboratories use a system to efficiently manage the time required to carry out certain test phases [20].

A medical laboratory is expected to have written documentation of instrument calibrations and verification of reagent preparation procedures. Documentation is the key to any quality system in the laboratory. There is a well-known golden rule of quality that reads: "If it's not written down, it didn't happen!" [8].

Laboratories apply appropriate standards when they wish to demonstrate their ability to apply a quality assurance system. For this purpose, international standards ISO 15189, ISO 17025 and ISO 9001, as well as corresponding national regulations and standards, are most often applied. A regulation is a document mandated by a government agency or authority. Standards can be developed at the international, national or local level. Medical laboratories apply standards adopted by several international organizations whose competence is standardization. In practice, the standards adopted by the following organizations are most often used: International Organization for Standardization (ISO), Clinical and Laboratory Standards Institute (CLSI), European Committee for Standardization (CEN) and World Health Organization (WHO). WHO has developed several standards for diagnostic laboratories for specific diseases (for example, polio, tuberculosis, influenza, measles) [7]. Apart from the international level, standards can be developed in one country. Their application is only related to laboratories that examine samples at the national level. National standards may be adopted by governmental organizations or may be developed by a recognized body. In some cases, national standards may be developed on the basis of appropriate international standards (for example, ISO standards), where it is necessary to adapt them to the culture and general situation of the country in question. Compliance of the laboratory's work with the standard may be required by competent authorities or other competent bodies. In addition, compliance may be voluntary.

Analytical staff in medical laboratories are often not familiar with how to take samples in the pre-analytical phase. This is often a serious source of analysis inconsistencies, which can affect the quality of the final test results. In order to limit errors in the pre-analytical phase, El-houcine Sebbar [21] designed a model for real-time blood sample information management in a medical laboratory.

Medical laboratory engineering students are trained to perform all activities in medical and related laboratories, including theoretical and practical knowledge in the

field of quality control and quality management. The aim of this paper is to show the requirements of quality management standards and analyze the possibility of participation of medical-laboratory engineering students in their application in the chemical laboratory where they are trained for the future profession.

### **Material and methods**

During the research in this paper, a review of several quality management standards was performed: ISO 9000, ISO 9001, ISO 17025 and ISO 15189. The authorized versions of the standards that the College of Health Sciences Prijedor purchased from the Institute for Standardization of Bosnia and Herzegovina were used. During the analysis, a comparison was made of the requirements given in the mentioned standards. On that occasion, areas were identified during the interpretation and practical application of which students can participate. A number of standard operating procedures and work instructions were developed, through the application of which the students contributed to improving the quality of laboratory results.

### **Results and discussion**

Quality management, which includes quality assurance and quality control of various processes in the laboratory, is necessary to ensure that the highest quality results are obtained, and that these results are obtained through valid, credible and standardized protocols [22].

#### *Standards and verification of the effectiveness of the quality management system in the laboratory*

Laboratories can demonstrate their ability to implement a quality management system in a number of ways. In principle, they apply accreditation, certification and licensing procedures. An independent external agency or internally appointed personnel on behalf of the laboratory management may conduct a periodic quality check of the laboratory's performance. Certification is used to verify the competence of personnel to perform certain tasks, and to verify whether products meet certain requirements. Accreditation is used to verify whether the laboratory applies an appropriate quality management system and whether it is capable of properly performing certain test methods. Accreditation is also applied when checking whether calibration laboratories are capable of carrying out calibration in accordance with their scope of accreditation [10].

ISO 17025:2017, ISO 15189:2012 and several WHO standards (for example, the WHO standard for polio) is determined. ISO 9001:2017 and ISO 14000:2015 standards are most often applied for medical laboratory certification. Of the regulations that laboratories must apply, the following should be mentioned: UN Transport of Dangerous Goods Regulations and UNDP Good Laboratory Practice, the mandatory application of which is conditioned by the adoption of national regulations in that area.

Given the large number of standards for quality system evaluation, the choice of standards to be applied by the laboratory depends on the type of laboratory and the scope of its work. However, the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) provided a common standard for evaluating laboratory competence [8]. ISO 15189 is an international standard that provides quality management system requirements for medical laboratories. The standard is provided by the International Organization for Standardization [23] and covers all steps relevant to laboratory tests performed to obtain information about a patient's health related to the diagnosis, treatment or prevention of disease. According to the requirements of the international standard BAS EN ISO 15189:2018, the laboratory must establish, document, implement and maintain a quality management system and continuously improve its effectiveness. The quality management system must ensure the integration of all processes necessary to fulfill the quality policy and objectives, and satisfy the needs and requirements of users.

ISO 15189 [24] is a globally recognized standard specifically created for medical laboratories to help them develop their quality management systems and assess their competencies. Also, it is applicable for confirmation or recognition of medical laboratory competencies by laboratory users, regulatory bodies and accreditation bodies. The aim of the ISO 15189 standard is to improve the well-being of patients and increase the satisfaction of laboratory users through trust in the quality and competence of medical laboratories. The standard requires medical laboratories to plan and implement activities to address risks and opportunities for improvement. This approach has multiple benefits (for example, increasing the efficiency of the management system, reducing the likelihood of invalid results, and reducing potential harm to patients, laboratory personnel, the public, and the environment).

The medical laboratory has an important role. It is essential for patient care. The laboratory provides activities within the ethical and management framework, which recognizes the obligations of healthcare providers towards the patient. These activities need to be undertaken in time, as this is the only way to meet the needs of all patients and staff responsible for patient care. The requirements of the standard refer to all activities that can affect the quality of results and the satisfaction of service users: examination and preparation of patients, identification of patients, collection of samples, transport, processing of patient samples, selection of analyzes that are suitable for the intended use, examination of samples, storage of samples, as well as subsequent interpretation, reporting of results and advice for laboratory users [24].

The ISO 15189 standard is intended for use in currently recognized medical laboratory disciplines, but can be effectively applied during the provision of other health services (for example, diagnostic imaging, respiratory therapy, physiological sciences, blood banks and transfusion services). The use of the ISO 15189 standard facilitates the cooperation of medical laboratories with other health services, helps in the exchange of information and the harmonization of methods and procedures. It is important to note that the application of standards enables the comparability of patient

examination results between several medical laboratories regardless of the place or country in which they work [24].

Management requirements refer to the requirements that the laboratory must meet in terms of organization, competence of the employed staff, and requirements for identifying and eliminating weaknesses/mistakes in the work environment. Preventive and corrective measures to be taken should be identified and implemented in time. Continuous process improvement should be incorporated into the work of the medical laboratory [10].

ISO 17025 [25] was developed with the aim of promoting confidence in the work of laboratory. The standard allows laboratories to demonstrate that they work competently and can provide valid results. The standard requires the laboratory to plan and implement measures related to risks and opportunities, and specifies general requirements for the competence, impartiality and consistent operation of the laboratory. This document is applicable to all organizations that perform laboratory activities, regardless of the type of testing and the number of staff. The use of this document facilitates the cooperation of the laboratory with other bodies and contributes to a more efficient exchange of information. In addition, the application of standards contributes to the harmonization of procedures carried out in laboratories. If the laboratories are compliant with the ISO 17025 standard, the acceptance of laboratory results in other countries is much easier. Accreditation bodies, regulatory bodies and users of laboratory services use this standard to confirm or recognize the competence of laboratories [25]. ISO 17025 [25] is applied by laboratories not involved in clinical work (for example, calibration laboratories or forensic science laboratories [10]. Laboratories that comply with this document will also operate, in a general sense, in accordance with the principles of the ISO 9001 standard.

The international standard ISO 9001 [26] specifies the requirements for a quality management system that allow the organization to demonstrate its ability to consistently provide products and services that meet the requirements of users and applicable laws and regulations, and when the organization aims to increase user satisfaction through the effective application of the system.

*Comparative overview of the requirements of the current versions of the following standards ISO 9001, ISO 17025 and ISO 15189*

The experience of a large number of medical laboratories shows that the requirements of the mentioned standards complement each other and enable laboratories to cover a greater number of areas of their work with the quality management system. Comparative overview of the requirements of the valid versions of the following standards ISO 9001, ISO 17025 and ISO 15189 (table 1) and comparative overview of the technical requirements given in the standards BAS EN ISO 15189:2018 (identical to EN ISO 15189: 2012) and ISO 15189:2022 (table 2) . The International Organization for Standardization (ISO) has published a new version of the standard ISO 15189:2022 "Medical Laboratories - Requirements for quality and competence" [27]. The standard specifies requirements for quality and competence in medical laboratories, and now includes requirements for the so-called

Point-of-care testing (POCT). POCT is a form of examination in which the examination is performed near or at the site of the patient. In the new version of the ISO 15189:2022 standard, the emphasis on risk management has increased. In addition, the standard is aligned with ISO/IEC 17025:2017. The Institute for Standardization of Bosnia and Herzegovina has started preparations for the download and translation of the new edition of the standard. The transitional period for the implementation of the requirements of the new edition of the standard is 3 years, that is, until December 2025. From the beginning of 2024, BATA plans to start evaluating all requests received by medical laboratories (approval/extension of accreditation) in accordance with the new edition of the standard.

Table 1. Comparative overview of the requirements of the current versions of the following standards ISO 9001, ISO 17025 and ISO 15189

<b>SRPS ISO 9001:2015 (identical to ISO 9001:2015)</b>	<b>BAS EN ISO/IEC 17025:2018 (identical to ISO/IEC 17025:2017)</b>	<b>BAS EN ISO 15189:2018 (identical to ISO 15189: 2012)</b>	<b>ISO 15189:2022</b>
1. Scope	1. Scope	1. Scope	1. Scope
2. Normative references	2. Normative references	2. Normative references	2. Normative references
3. Terms and definitions	3. Terms and definitions	3. Terms and definitions	3. Terms and definitions
	4. General requirements		4. General requirements
4. Context of the organization	5. Structural requirements		5. Structural and governance requirements
		4. Management requirements	
5. Leadership			
6. Planning			
7. Support	6. Resource requirements	5. Technical requirements	6. Resource requirements
8. Operation	7. Process requirements		7. Process requirements
	8. Management system requirements		8. Management system requirements
9. Performance evaluation			
10. Improvement			
			Annex A. Additional requirements for Point-of-Care Testing (POCT)

Technical requirements refer to the conditions that must be met during the construction of medical laboratories. These conditions should ensure efficient work, safety and comfort of workers. In addition, the BAS EN ISO 15189:2018 standard contains requirements regarding the procurement and maintenance of the required amount of reagents and other consumables, regarding the method of storing materials and keeping information. The ISO 15189 standard requires that the laboratory has appropriate software and preferably uses a laboratory information system. In an effort to maintain data integrity and reduce the impact and severity of unplanned downtime and adverse events, the laboratory must have a documented backup system. The information system must have data protection and recovery in case of hardware and/or software failure [10]. The medical laboratory must prepare and properly and meticulously keep records. This enables unhindered timely reporting and reconfirmation of reported results. When it comes to equipment, standards define the minimum basics for the acquisition and storage of laboratory equipment and are directly related to laboratory productivity and valid reporting [10].

The new version of the ISO 15189:2022 standard is harmonized with the ISO 17025:2017 standard in the part of general requirements, which refer to impartiality, confidentiality of research and requirements regarding patients. A laboratory must be responsible for impartiality during its laboratory activities and must not allow commercial, financial or other pressures to compromise impartiality [1]. A threat to the laboratory's impartiality can be represented by participation in the ownership, management and leadership of the laboratory, and family relationship with the employed staff, use of common resources, participation in the financing of the laboratory, the existence of commercial and marketing agreements (including branding), payment of a percentage of sales or other benefits to attract new users, etc. The laboratory must identify risks to its impartiality. When identifying a risk to impartiality, the laboratory must be able to demonstrate the ability to eliminate or minimize that risk. The laboratory must be responsible for the management of all information received or generated during the performance of laboratory activities. The laboratory must inform the user in advance about the information it intends to make publicly available.

As can be seen from Table 2, the 2022 version of the standard contains new or more detailed requirements for resources, which in the earlier version were listed in the Technical Requirements chapter. Special emphasis should be placed on requirements related to equipment calibration and provision of metrological traceability, in connection with service contracts and externally provided products. In the Process Requirements chapter, requirements related to non-compliant work and user complaints have been added. Continuity planning and emergency preparedness have also been added in the new version of the standard.

Table 2. Comparative overview of technical requirements given in standards BAS EN ISO 15189:2018 (identical to EN ISO 15189: 2012) and ISO 15189:2022

<b>BAS EN ISO 15189:2018 (identical to EN ISO 15189: 2012)</b>	<b>ISO 15189:2022</b>
	4. General requirements
	4.1 Impartiality
	4.2 Confidentiality
	4.3 Requirements regarding patients
5. Technical requirements	6. Resource requirements
	6.1 General
5.1 Personnel	6.2 Personnel
5.2. Accommodation and environmental conditions	6.3 Facilities and environmental conditions
5.3 Laboratory equipment, reagents, and consumables	6.4 Equipment
	6.5 Equipment calibration and metrological traceability
	6.6 Reagents and consumables
	6.7 Service agreements
	6.8 Externally provided products and services
	7. Process requirements
	7.1 General
5.4 Pre-examination processes	7.2 Pre-examination processes
5.5 Examination processes	7.3 Examination processes
5.7 Post-examination processes	7.4 Post-examination processes
5.8 Reporting of results	
5.9 Release of results	
5.6 Ensuring quality of examination results	7.5 Nonconforming work
	7.7 Complaints
5.10 Laboratory information management	7.6 Control of data and information management
	7.8 Continuity and emergency preparedness planning

*Overview of the number of accredited laboratories in Bosnia and Herzegovina*

Most testing laboratories apply and accredit quality according to the ISO/IEC 17025 standard. This standard provides general requirements for the competence of testing and calibration laboratories and is universally recognized worldwide.

Standard was developed with the aim of promoting trust in laboratory work [7]. Based on the requirements contained in this standard, laboratories can demonstrate that they work competently and are capable of providing valid results. Laboratories that comply with this document work in accordance with the principles of the ISO 9001 standard. Organizations use the ISO 9001 standard to demonstrate the ability to consistently provide products and services that meet customer and regulatory requirements, which is associated with the concept of quality.

A good quality management system in a chemical laboratory should cover all aspects of work: organization, personnel, facilities and security, equipment, procurement, process control, information management, documents and records, quality assessment, process improvement, customer service and more.

The majority of laboratories in Bosnia and Herzegovina understood the importance of applying standards for the purpose of improving quality. In twenty years, significant results have been achieved in this regard. Laboratories received confirmation of their capabilities through the accreditation process. According to the data of the BiH Accreditation Institute [27], which maintains a register of accredited bodies for assessing compliance with the data of the area and scope of accreditation, the largest number of laboratories accredited their work in accordance with the BAS EN ISO/IEC 17025 standard (92 test laboratories and 11 calibration laboratories). (table 3). According to this report, only 4 medical laboratories are accredited according to the BAS EN ISO 15189 standard. For a number of laboratories, the BiH Accreditation Institute has suspended accreditation in whole or in part (table 3). In addition, several laboratories have submitted a request for the temporary suspension of a part of the area for which they are already accredited.

Table 3. Overview of the number of laboratories accredited in accordance with the BAS EN ISO/IEC 17025 standard

Standard ISO 17025 <sup>1</sup>	Accredited	Accreditation has been suspended
Test laboratories	92	9
Calibration laboratories	11	2
Standard ISO BAS EN ISO 15189 <sup>1</sup>	Accredited	Accreditation has been suspended
Medical laboratories	4	0

<sup>1</sup> Institute for accreditation of Bosnia and Herzegovina in 2023.

[http://www.bata.gov.ba/Akreditirana\\_tijela/](http://www.bata.gov.ba/Akreditirana_tijela/)

The International Organization for Standardization (ISO) keeps track of the number of organizations in the world that are certified according to twelve ISO management standards. Table 4 provides an overview of organizations in Bosnia and Herzegovina, which are certified in accordance with the ISO 9001 and ISO 13485 standards [28]. In the overview given on the ISO website, no medical laboratories are singled out, but it is to be expected that a number of laboratories have certified their

management system in accordance with ISO 9001. The ISO 13485 standard refers to medical equipment, so it is possible for some laboratories to be certified in accordance with this standard (table 4).

Table 4. Overview of organizations in Bosnia and Herzegovina that are certified in accordance with ISO 9001 and ISO 13485 standards

Year/State	Bosnia and Herzegovina	Year/State	Bosnia and Herzegovina
Standard ISO 9001 <sup>1</sup>		Standard ISO 13485 <sup>1</sup>	
2015	790	2015	0
2016	1037	2016	0
2017	1140	2017	6
2018	1,346	2018	3
2019	935	2019	26
2020	1145	2020	3
2021	1326	2021	3

<sup>1</sup> ISO, "ISO. 2022. The ISO Survey". Available: <https://www.iso.org/the-iso-survey.html>. [Last approach 10 5 2022]

## Conclusion

Changes to relevant standards will continue to meet testing and analyst needs. This requires new knowledge and new skills that medical laboratory engineering students should acquire during their studies. Knowledge of the quality management system in the laboratory and the requirements of relevant international standards will enable graduates to fit into the work of medical laboratories more easily.

## References

- [1] BAS EN ISO/IEC 17025:2018
- [2] BAS EN ISO 15189:2018
- [3] KA Sikaris, Enhancing the clinical value of medical laboratory testing, Clin. Biochem. Rev. 38 (3) (2017) 107–114.
- [4] Wallace P, McCulloch E. Quality Assurance in the Clinical Virology Laboratory. Encyclopedia of Virology [Internet]. 2021 [cited 2022 Aug 12]; 64–81. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7917444/>
- [5] Hooijberg EH. Quality Assurance for Veterinary In-Clinic Laboratories. Veterinary Clinics of North America: Small Animal Practice. 2023 Jan;53(1):1–16.
- [6] Reeuwijk V. Guidelines for quality management in soil and plant laboratories. Rome: Fao; 1998. ISBN 92-5-1040656. <https://www.fao.org/3/W7295E/w7295e00.htm#Contents>. Available on 05/24/2023
- [7] World Health Organization, Clinical And Laboratory Standards Institute, Centers For Disease Control And Prevention (U.S. Laboratory quality management system : handbook. Geneva: World Health Organization; 2011.
- [8] Farrell-Evans M, Warren W. Food Safety Assurance Systems: Quality Assurance and Good Laboratory Practice. Encyclopedia of Food Safety. 2014; 293–300. doi:10.1016/B978-0-12-378612-8.00374-7

- [9] Pawar SD, Kode SS, Keng SS, Tare DS, Abraham P. Steps, Implementation and Importance of Quality Management in Diagnostic Laboratories with Special Emphasis on Coronavirus Disease-2019. *Indian Journal of Medical Microbiology* [Internet]. 2020 Jul 1; 38(3):24351. Available from: <https://www.sciencedirect.com/science/article/pii/S0255085720315280?via%3Dihub>
- [10] Ikram A., Guenther R. and Rusek B. Good Clinical Laboratory Practices in Pakistan 2019 Pakistan Academy of Sciences in collaboration with (NASEM) [Internet]. [cited 2023 Aug 29]. Available from: <https://www.nih.org.pk/wp-content/uploads/2019/04/HANDBOOK-for-Good-Clinical-Lab.pdf>
- [11] Arnold JE, Camus MS, Freeman KP, Giori L, Hooijberg EH, Jeffery U, et al. ASVCP Guidelines: Principles of Quality Assurance and Standards for Veterinary Clinical Pathology (version 3.0). *Veterinary Clinical Pathology*. 2019 Dec; 48(4):542–618. doi:10.1111/vcp.12810
- [12] van Rossum HH. Moving average quality control: principles, practical application and future perspectives. *Clinical Chemistry and Laboratory Medicine (CCLM)*. 2018 Oct 11; 57(6):773–82. DOI: [10.1515/cclm-2018-0795](https://doi.org/10.1515/cclm-2018-0795)
- [13] Loh TP, Cervinski MA, Katayev A, Bietenbeck A, van Rossum H, Badrick T. Recommendations for laboratory informatics specifications needed for the application of patient-based real time quality control. *Clinica Chimica Acta* [Internet]. 2019 Aug 1 [cited 2022 Sep 12]; 495:625–9. <https://doi.org/10.1016/j.cca.2019.06.009>
- [14] Ng DP, Polito FA, Cervinski MA. Optimization of a Moving Averages Program Using a Simulated Annealing Algorithm: The Goal is to Monitor the Process Not the Patients. *Clinical Chemistry*. 2016 Oct 1; 62(10):1361–71. <https://doi.org/10.1373/clinchem.2016.257055>
- [15] van Rossum HH, Kemperman H. Implementation and application of moving average as continuous analytical quality control instrument demonstrated for 24 routine chemistry assays. *Clinical Chemistry and Laboratory Medicine (CCLM)*. 2017 Jul 26; 55(8):1142–51. DOI:10.1515/cclm-2016-0696
- [16] Bietenbeck A, Thaler MA, Luppa PB, Klawonn F. Stronger Together: Aggregated Z-values of Traditional Quality Control Measurements and Patient Medians Improve Detection of Biases. *Clinical Chemistry*. 2017 Aug 1; 63(8):1377–87. DOI: [10.1373/clinchem.2016.269845](https://doi.org/10.1373/clinchem.2016.269845)
- [17] OECD SERIES ON PRINCIPLES OF GOOD LABORATORY PRACTICE AND COMPLIANCE MONITORING Number 1 OECD Principles on Good Laboratory Practice (as revised in 1997) [Internet]. [cited 2022 Dec 2]. Available from: [https://one.oecd.org/document/ENV/MC/CHEM\(98\)17/en/pdf](https://one.oecd.org/document/ENV/MC/CHEM(98)17/en/pdf)
- [18] QMS02-A6 Quality Management System: Development and Management of Laboratory Documents; Approved Guideline-Sixth Edition. A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process. S A M P L E [Internet]. 2013 [cited 2023 Aug 30]. Available from: [https://clsi.org/media/2493/qms02a6e\\_sample.pdf](https://clsi.org/media/2493/qms02a6e_sample.pdf)
- [19] Park M, Kim YJ, Jung D, Kim Y, Kim HM, Lee Y, et al. Quality improvement of outpatient clinical chemistry tests through a novel middleware-laboratory information system solution. *Clinical Biochemistry*. 2023 Mar; 113:21–8. <https://doi.org/10.1016/j.clinbiochem.2022.12.017>
- [20] Howanitz JH, Howanitz PJ. Laboratory Results. *American Journal of Clinical Pathology*. 2001 Sep; 116(3):311–5. DOI: [10.1309/H0DY-6VTW-NB36-U3L6](https://doi.org/10.1309/H0DY-6VTW-NB36-U3L6)
- [21] El-houcine Sebbar, Mourad Rehali, Abderrazak Saddari, Azghar A, Choukri M. A device model for the management of information concerning blood samples in real time

- in the medical biology laboratory. Materials Today: Proceedings. 2023 Jan 1; 72:3594–6.  
<https://doi.org/10.1016/j.matpr.2022.08.381>
- [22] Chaudhery Mustansar Hussain, Deepak Rawtani, Pandey G, Maithri Tharmavaram. Quality control and quality assurance in forensic science laboratories. 2021 Jan 1; <https://doi.org/10.1016/B978-0-12-822300-0.00022-7>
- [23] International Organization for Standardization. ISO 15189:2014: medical laboratories – requirements for quality and competence [ISO 15189:2012, Corrected version 2014-08-15], 2014.
- [24] ISO 15189:2017. Medical laboratories—special requirements for quality and competence. Geneva: standard.
- [25] ISO/IEC 17025:2005. General requirements for the competence of testing and calibration laboratories. Geneva:
- [26] ISS. 2015. SRPS ISP 9001:2015. Quality management systems — Requirements (Quality management systems — Requirements) Reference mark SRPS ISO 9001:2015 (sr, en) (Identical to ISO 9001:2015
- [27] BATA. 2023. List of accredited bodies for conformity assessment as of 2023-03-29. Institute for Accreditation of Bosnia and Herzegovina. Available on the site. [http://www.bata.gov.ba/Akreditirana\\_tijela/](http://www.bata.gov.ba/Akreditirana_tijela/) (Access to the site 10.05.2023)
- [28] ISO. "ISO. 2022. The ISO Survey.," [Online]. Available: <https://www.iso.org/the-iso-survey.html>. [Last accessed 10 5 2022]

## SAVREMENI TRENDOWI U UNAPREĐENJU SISTEMA UPRAVLJANJA KVALITETOM U HEMIJSKOJ LABORATORIJI

***Radoslav Grujić<sup>1</sup>, Mira Obradović<sup>1</sup>***

<sup>1</sup> JU Visoka medicinska škola Prijedor, Nikole Pašića 4A, Prijedor,  
Republika Srpska, Bosna i Hercegovina

**Sažetak.** *Medicinske i kliničke laboratorije imaju važnu ulogu u sistemu zdravstvene zaštite stanovništva. Efikasnost ukupnog sistema i uspjeh u dostizanju postavljenih ciljeva zavise od sistema upravljanja kvalitetom u organizacijama čija djelatnost se odnosi na ispitivanje uzoraka materijala dobijenog iz ljudskog tijela. Važeći propisi su najčešće generičkog karaktera. Zahtjeve sistema upravljanja kvalitetom laboratorija treba prilagoditi uslovima i konkretnim radnim aktivnostima. Cilj ovog rada je da se prikažu zahtjevi standarda upravljanja kvalitetom i analizira mogućnost njihove primjene u hemijskoj laboratoriji u kojoj se obučavaju studenti medicinsko-laboratorijskog inženjerstva. U radu je dat pregled ključnih zahtjeva tri standarda: ISO 9001, ISO 15189 i ISO 17025. Standard ISO 9001 je namijenjen za certifikaciju laboratorija svih vrsta i veličina, uključujući i medicinsko-zdravstvene laboratorije, dok je standard ISO 17025 namijenjen za primjenu i akreditaciju svih laboratorija koje se bave ispitivanjem i kalibracijom. Standard ISO 15189, koji je baziran na Principima dobre laboratorijske prakse, namijenjen je za primjenu isključivo u medicinsko-zdravstvenim laboratorijama. Prema zahtjevima ISO 9001 ispunjenje svih zahtjeva treba rezultirati zadovoljstvom klijenata i potpunom usklađenosti sa propisima. Standard je zasnovan na određenim principima, međutim standard ne sadrži tehničke zahtjeve specifične za laboratorije. Sa druge strane standard ISO 15189 je fokusiran na tehničke zahtjeve za medicinsko-zdravstvene laboratorije, uključujući laboratorije za hemijska ispitivanja. Ovaj standard prilagođava zahtjeve ISO 17025 za primjenu medicinsko-zdravstvenim laboratorijama.*

*Zahtjevi standarda ISO 15189 su komplementarni sa važećim propisima i značajno dopunjuju njihovu primjenu u praksi. Na osnovu analize važećih verzija standarda upravljanja kvalitetom, može se zaključiti da je za hemijske laboratorije poželjno da istovremeno implementiraju standarde ISO 9001 i ISO 15189 uz uvažavanje službenih propisa u ovoj oblasti.*

**Ključne riječi:** *Medicinsko-zdravstvene laboratorije, hemijska laboratorija, Sistem upravljanja kvalitetom, ISO 9001, ISO 15189, ISO 17025*